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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,066	09/24/2004	Ulrich Abel	12874-00001-US	1371
23416 7590 01/06/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER DESAL, RITA J				
ART UNIT 1625		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,066

Applicant(s)

ABEL ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/08 has been entered.

Claims pending 1-7, 9, 15-17 are pending.

Claim 17 is new.

Arguments and Response

Rejection under 35 USC first para written description.

The applicants argue that the rejection was given in the first office action because the heterocyloco and heteroaryls are not defined.

Yes according to the specifications some examples are given. On pages 13 and 14.

However the generic language as given in the claims covers a lot of variable and the specifications do not have enough examples to show that the full scope has been reduced to practice.

Applicants have amended the claims to include

wherein heterocycloalkyl by itself or as part of another substituent means cycloalkyl groups, wherein up to two CH₂ groups may be substituted by oxygen, sulfur or nitrogen atoms, and one or two other CH₂ groups may be substituted by one or two carbonyl function(s), carbothionyl function(s), or a carbonyl function and a carbothionyl function, and
wherein heteroaryl by itself or as part of another substituent means aromatic ring systems with up to 3 rings and with up to 3 identical or different heteroatoms N, S, O, in which at least 1 ring system is aromatic, and those with up to 3 substituents, preferably up to 1 substituent, wherein the substituents independently can have the meaning C₁-C₆ alkyl, OH, NO₂, CN, CF₃, OR11, SH, SR11, C₁-C₆ alkylhydroxy, C₁-C₆ alkyl-OR11, COOH, COOR11, NH₂, NHCOR11,

The generic terminology of rings has so many permutations and combinations that applicants examples constitute only a small fraction and does not correspond to the reduction of the full scope of the claimed compounds.

The compounds in table 1-3 have examples where only the R of diagram 3 and R2 of diagram 5 as given on pages 17 and 20-45 of the specifications. A limited number of hetero group substituents are shown.

Applicants claims are very broad.

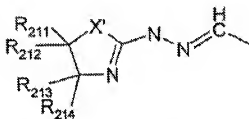
The substituents are given on several pages for example

R1 means H, C₁-C₆ alkyl, cyclically, or C₁-C₄ alkylcycloalkyl,

R3 means H and

R2 means H, C₁-C₁₄ alkyl, C₂-C₁₄ alkenyl, aryl, C₁-C₄ alkylaryl, heteroaryl, C₁-C₄ alkylheteroaryl, C₂-C₄ alkenylheteroaryl, cycloalkyl, C₁-C₄ alkylcycloalkyl, heterocycloalkyl, C₁-C₄ alkylheterocycloalkyl, C_mH_{2m+o-p}Y_p (with m = 1 to 6, for o = 1, p = 1 to 2m+o; for m = 2 to 6, o = -1, p = 1 to 2m+o; for m = 4 to 6, o = -2, p = 1 to 2m+o; Y = independently selected from the group consisting of halogen, OH, OR21, NH₂, NHR21, NR21R22, and SH, SR21), (CH₂)_nCH₂NHCOR21, (CH₂)_nCH₂OCOR21, (CH₂)_nCH₂NHCSR21, (CH₂)_nCH₂S(O)nR21, with n = 0, 1, 2, (CH₂)_nCH₂SCOR21, (CH₂)_nCH₂OSO₂-R21, (CH₂)_nCHO, (CH₂)_nCH=NOH,

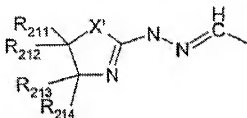
$(\text{CH}_2)_3\text{CH}(\text{OH})\text{R}_{21}$, $-(\text{CH}_2)_3\text{CH}=\text{NOR}_{21}$, $(\text{CH}_2)_3\text{CH}=\text{NOCOR}_{21}$,
 $(\text{CH}_2)_3\text{CH}=\text{NOCH}_2\text{CONR}_{21}\text{R}_{22}$, $(\text{CH}_2)_3\text{CH}=\text{NOCH}(\text{CH}_3)\text{CONR}_{21}\text{R}_{22}$,
 $(\text{CH}_2)_3\text{CH}=\text{NOC}(\text{CH}_3)_2\text{CONR}_{21}\text{R}_{22}$, $(\text{CH}_2)_3\text{CH}=\text{N-NHCO-R}_{23}$, $(\text{CH}_3)_3\text{CH}=\text{N-NHC}(\text{O})\text{NHR}_{23}$, $(\text{CH}_2)_3\text{CH}=\text{N-NHC}(\text{S})\text{NHR}_{23}$, $(\text{CH}_2)_3\text{CH}=\text{N-NHC}(\text{NH})\text{NHR}_{23}$, $(\text{CH}_2)_3\text{CH}=\text{N-NHC}(\text{NH})\text{R}_{23}$, $(\text{CH}_2)_3\text{CH}=\text{N-NHCO-CH}_2\text{NHCOR}_{21}$, $(\text{CH}_2)_3\text{CH}=\text{N-O-CH}_2\text{NHCOR}_{21}$,
 $(\text{CH}_2)_3\text{CH}=\text{N-NHCS-R}_{23}$, $(\text{CH}_2)_3\text{CH}=\text{CR}_{24}\text{R}_{25}$ (trans or cis), $(\text{CH}_2)_3\text{COOH}$, $(\text{CH}_2)_3\text{COOR}_{21}$,
 $(\text{CH}_2)_3\text{CONR}_{21}\text{R}_{22}$, $-(\text{CH}_2)_3\text{CH}=\text{NR}_{21}$, $(\text{CH}_2)_3\text{CH}=\text{N-NR}_{21}\text{R}_{22}$,



, and the $(\text{CH}_2)_3$ -chain elongated group $(\text{CH}_2)_3\text{CH}=\text{N-N}-(\text{C}_3\text{NX}'\text{R}_{211}\text{R}_{212}\text{R}_{213}\text{R}_{214})$ (with $\text{X}' = \text{NR}_{215}$, O, S, and R_{211} , R_{212} , R_{213} , R_{214} , R_{215} being independently H or $\text{C}_1\text{-C}_6$ alkyl), -
 $(\text{CH}_2)_3\text{CH}=\text{N-NHSO}_2$ aryl, or $(\text{CH}_2)_3\text{CH}=\text{N-NHSO}_2$ heteroaryl, with $r = 0, 1, 2, 3, 4, 5$,
 or

R_3 means F, Cl, Br, I, OH, OR₃₁, NO₂, NH₂, NHR₃₁, NR₃₁R₃₂, NHCHO, NHCOR₃₁,
 NHCOCF₃, $\text{CH}_2\text{-m-hal}_m$ (with hal = Cl, F, and $m = 1, 2, 3$), or OCOR₃₁, and
 R_2 means H, $\text{C}_1\text{-C}_{14}$ alkyl, $\text{C}_2\text{-C}_{14}$ alkenyl, aryl, $\text{C}_1\text{-C}_4$ alkylaryl, heteroaryl, $\text{C}_1\text{-C}_4$
 alkylheteroaryl, $\text{C}_2\text{-C}_4$ alkenylheteroaryl, cycloalkyl, $\text{C}_1\text{-C}_4$ alkylcycloalkyl, heterocycloalkyl,
 $\text{C}_1\text{-C}_4$ alkylheterocycloalkyl, $\text{C}_m\text{H}_{2m+2}\text{-Y}_p$ (with $m = 1$ to 6 , $o = 1$, $p = 1$ to $2m+1$; for $m = 2$ to
 6 , $o = -1$, $p = 1$ to $2m+1$; for $m = 4$ to 6 , $o = -2$, $p = 1$ to $2m+1$; Y = independently selected from
 the group consisting of halogen, OH, OR₂₁, NH₂, NHR₂₁, NR₂₁R₂₂, and SH, SR₂₁),
 $(\text{CH}_2)_3\text{CH}_2\text{NHCOR}_{21}$, $(\text{CH}_2)_3\text{CH}_2\text{OCOR}_{21}$, $(\text{CH}_2)_3\text{CH}_2\text{NHCSR}_{21}$, $(\text{CH}_2)_3\text{CH}_2\text{SC}(\text{O})\text{mR}_{21}$, with n
 $= 0, 1, 2$, $(\text{CH}_2)_3\text{CH}_2\text{SCOR}_{21}$, $(\text{CH}_2)_3\text{CH}_2\text{OSO}_2\text{-R}_{21}$, $(\text{CH}_2)_3\text{CHO}$, $(\text{CH}_2)_3\text{CH-OH}$,
 $(\text{CH}_2)_3\text{CH}(\text{OH})\text{R}_{21}$, $-(\text{CH}_2)_3\text{CH}=\text{NOR}_{21}$, $(\text{CH}_2)_3\text{CH}=\text{NOCOR}_{21}$,
 $(\text{CH}_2)_3\text{CH}=\text{NOCH}_2\text{CONR}_{21}\text{R}_{22}$, $(\text{CH}_2)_3\text{CH}=\text{NOCH}(\text{CH}_3)\text{CONR}_{21}\text{R}_{22}$,

$(\text{CH}_2)_r\text{CH}=\text{NOC}(\text{CH}_2)_r\text{CONR}21\text{R}22$, $(\text{CH}_2)_r\text{CH}=\text{N-NHCO-R}23$, $(\text{CH}_2)_r\text{CH}=\text{N-NHC}(\text{ONH})\text{-R}23$, $(\text{CH}_2)_r\text{CH}=\text{N-NHC}(\text{S})\text{NH-R}23$, $(\text{CH}_2)_r\text{CH}=\text{N-NHC}(\text{NH})\text{NH-R}23$, $(\text{CH}_2)_r\text{CH}=\text{N-NHC}(\text{NH})\text{-R}23$, $(\text{CH}_2)_r\text{CH}=\text{N-NHCO-CH}_2\text{NHCOR}21$, $(\text{CH}_2)_r\text{CH}=\text{N-O-CH}_2\text{NHCOR}21$, $(\text{CH}_2)_r\text{CH}=\text{N-NHCS-R}23$, $(\text{CH}_2)_r\text{CH}=\text{CR}24\text{R}25$ (trans or cis), $(\text{CH}_2)_r\text{COOH}$, $(\text{CH}_2)_r\text{COOR}21$, $(\text{CH}_2)_r\text{CONR}21\text{R}22$, $-(\text{CH}_2)_r\text{CH}=\text{NR}21$, $(\text{CH}_2)_r\text{CH}=\text{N-NR}21\text{R}22$,



and the $(\text{CH}_2)_r$ -chain elongated group $(\text{CH}_2)_r\text{CH}=\text{N-N-(C}_3\text{NX'R}211\text{R}212\text{R}213\text{R}214)$ (with X' = NR₂₁₅, O, S, and R₂₁₁, R₂₁₂, R₂₁₃, R₂₁₄, R₂₁₅ being independently H or C₁-C₆ alkyl), $(\text{CH}_2)_r\text{CH}=\text{N-NHSO}_2$ aryl or $-(\text{CH}_2)_r\text{CH}=\text{N-NHSO}_2$ heteroaryl, with $r = 0, 1, 2, 3, 4, 5$,

R₂₁, R₂₂ are independently H, C₁-C₁₄ alkyl, C₁-C₁₄ alkanoyl, C₁-C₆ alkylhydroxy, C₁-C₆ alkoxy, C₁-C₆ alkylamino, C₁-C₆ alkylamino-C₁-C₆ alkyl, C₁-C₆ alkylamino-di-C₁-C₆ alkyl, cycloalkyl, C₁-C₄ alkylcycloalkyl, heterocycloalkyl, C₁-C₄ alkylheterocycloalkyl, aryl, aryloyl, C₁-C₄ alkylaryl, heteroaryl, heteroaryloyl, C₁-C₄ alkylheteroaryl, cycloalkanoyl, C₁-C₄ alkanoylcycloalkyl, heterocycloalkanoyl, C₁-C₄ alkanoylheterocycloalkyl, C₁-C₄ alkanoylaryl, C₁-C₄ alkanoylheteroaryl, mono- and di-sugar groups linked through a C atom which would carry an OH group in the sugar, wherein the sugars are independently selected from the group consisting of glucuronic acid and its stereoisomers at all optical atoms, aldopentoses, aldohexoses, including their desoxy compounds (as e.g. glucose, desoxyglucose, ribose, desoxyribose), or R₂₁ and R₂₂, together with the N, form a ring with 4, 5, 6, 7, or 8 members, which may optionally contain still another heteroatom selected from the group N, O, and S,

R₂₃ independently of R₂₁, has the same meanings as R₂₁, or CH₂-pyridinium salts, CH₂-tri-C₁-C₆ alkylammonium salts, CONH₂, CSNH₂, CN, or CH₂CN,

¹⁴⁵

R24 independently of R21, has the same meanings as R21, or H, CN, COCH₃, COOH, COOR21, CONR21R22, NH₂, or NHCOR21,

R25 independently of R21, has the same meanings as R21, or H, CN, COCH₃, COOH, COOR21, CONR21R22, NH₂, or NHCOR21,

R24, R25 together with the N, form a ring with 4, 5, 6, 7, or 8 members, which may optionally contain still another heteroatom selected from the group N, O, and S,

R3 means H, F, Cl, Br, I, OH, OR31, NO₂, NH₂, NHR31, NR31R32, NHCOR31, NHCOCF₃, CH₂-hal_m (with hal = Cl, F, and m = 1, 2, 3), or OCOR31,

R31, R32 are independently C₁-C₆ alkyl, or R31 and R32, together with the N, form a ring with 4, 5, 6, 7, or 8 members, which may optionally contain still another heteroatom selected from the group N, O, and S,

R5 means H, C₁-C₂₀ alkyl, cycloalkyl, C₂-C₂₀ alkenyl, C₂-C₁₀ alkynyl, C₁-C₄ alkylcycloalkyl, heterocycloalkyl, C₁-C₄ alkylheterocycloalkyl, aryl, C₁-C₄ alkylaryl, heteroaryl, C₁-C₄ alkylheteroaryl, C_mH_{2m+o+p}Y_p (with m = 1 to 6, for o = 1, p = 1 to 2m+o, for m = 2 to 6, o = -1, p = 1 to 2m+o; for m = 4 to 6, o = -2, p = 1 to 2m+o; Y = independently selected from the group consisting of halogen, OH, OR51, NH₂, NHR51, NR51R52, SH, SR21), (CH₂)₂CH₂NHCOR51, (CH₂)₂CH₂NHCSR51, (CH₂)₂CH₂S(O)_nR51, with n = 0, 1, 2, (CH₂)₂CH₂SCOR51, (CH₂)₂CH₂OCOR51, (CH₂)₂CH₂OSO₂-R51, (CH₂)₂CH(OH)R51, (CH₂)₂COOH, (CH₂)₂COOR51, (CH₂)₂CONR51R52, with s = 0, 1, 2, 3, 4, 5, mono- and di-sugar groups linked through a C atom which would carry an OH group in the sugar, wherein the sugars are independently selected from the group consisting of glucuronic acid and its stereo isomers at all optical atoms, aldopentoses, aldohexoses, including their desoxy compounds (as e.g. glucose, desoxyglucose, ribose, desoxyribose), with the mono-sugar groups such as aldopentoses, aldohexoses, including

According to MPEP written description requires that a sufficient amount of reduction to practice
Corresponding to the scope of the claimed invention.

Fujikawa v. Wattanasin (39 USPQ2d 1895) held that 'a "laundry list" disclosure of every possible moiety does not constitute written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species'

Thus the rejection under 35 USC written description still stands.

The rejection under 35 US 112 first para scope of enablement also still stands. The arguments have been considered but not found to be convincing. Also see above rejection. Pharmaceutical art coupled with the art of Organic synthesis is highly unpredictable and as explained by the examiner before applicants have not provided sufficient guidance for the same.

Applicants have now further added even a more generic definition for the groups which makes the claims further not enabled.

See

Ex parte DIAMOND, 123 USPQ 167 (Bd. Pat. App. & Int. 1959) where the examiner was affirmed for a scope of enablement rejection, and the court stated:

Scope of claims should not be unduly extensive in chemical fields where applicability is highly speculative or not explored; subject matter which relies upon prediction for its support is unpatentable.

Specification contains 23 specific examples, but they are to preparation of relatively simple compounds; this is relatively meager and non representative disclosure to support claims embracing millions of compounds.

Applicant may not preempt unduly large field by expedient of making broad prophetic statements in specification and claims unless accuracy of such statements is sufficiently supported by well established chemical principles or by sufficient number of examples. "The term 'substituted' without modification or restriction includes all compounds wherein one or more of the atoms or radicals of the original compound have been replaced by one or more other atoms or radicals. Without any limitation on the character or number of substituents it becomes apparent that the quoted term may be considered inclusive of almost any possible

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substance and the claims under consideration are either of unlimited or indeterminate scope. We are of the opinion that the reasoning of the courts in *Schering Corp. v. Gilbert*, 68 USPQ 84, and *Hercules Powder Co. v. Rohm & Haas*, 70 USPQ 297, is controlling.”

embrace millions of compounds. It should also be observed that appellant is working in a field where little prediction is possible and this Board has on several occasions held that the scope of claims should not be unduly extensive in fields where applicability is highly speculative or not explored and that subject matter which relies upon prediction for its support is unpatentable. *Ex parte Middleton*, 87 USPQ 57; *Ex parte Kauck et al.*, 95 USPQ 197, *Ex parte Rosenkranz et al.*, Pat. No. 2,715,637.

In Minnesota Mining and Mfg. Co. et al. v. Carborundum Co. et al., 155 F.2d 746, 69 USPQ 288, the court held that “An inventor cannot disclose a small number of components which will serve as a springboard for claiming an entire class.”

In addition *In re Fouché* 169 USPQ 429 dealt with a similar issue with respect to how to use requirement of 112 1st paragraph,

“Inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention; nevertheless, applicant must use some technique of providing teaching of how to use which is commensurate with breadth of protection sought by claim, unless such knowledge is already available to persons skilled in the art; thus, where applicant undertakes to define invention by recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of group.

Both the examiner and the board noted that none of the working examples pertained to compounds wherein Z was heterocyclic. Appellant is quite correct in contending that, under our decisions in *In re Robins*, 57 CCPA 1321, 429 F.2d 452, 166 USPQ 552 (1970), the inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention. Nevertheless, an applicant must use *some* technique of providing teaching of how to use which is commensurate with the breadth of protection sought by the claim, unless such knowledge is already available to persons skilled in the art.

It seems clear, and it is not disputed by appellant, that where an applicant undertakes to define his invention by the recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of the Markush group. The examiner and the board did not believe that appellant had done so as to the heterocyclic members of the group. While they noted the absence of examples using heterocyclic moieties, we do not find that they viewed examples as mandatory. The issue before us is whether appellant has provided *any* teaching of how to use compounds containing the heterocyclic members of the Markush group. The only reference to heterocyclic radicals in the specification is the statement that “the invention provides” compounds of the structure shown in claim 1, wherein Z may be, among other possibilities,

a mononuclear, nitrogen-containing heterocycle connected to the chain A by the nitrogen atom, and optionally containing an oxygen, sulphur, or second nitrogen atom in the ring and optionally

substituted by one of more alkyl radicals containing 1 to 5 carbon atoms each, such as 1-pyrrolidyl, piperidino, morpholino, 1-piperaziny, or 4-alkyl-1-piperaziny. "

See *Ex parte WEIL AND SCHLICHTING*, 158 USPQ 620 (Bd. Pat. App. & Int. 1967)

"We will sustain this rejection of the claims as we are in accord with the examiner's position. We find no support in the disclosure for such compounds encompassed by these claims wherein R 1, R 2, R 3, and R 5 are all the same and selected from the group, lower alkyl, hydroxy, alkoxy, di(loweralkyl)amino and nitro for example. These claims appear to be in the nature of a paper concept wherein all possible substituents have been included in the composition. There are no examples of such compounds which are included within the vast scope encompassed by these claims, although appellants have a considerable disclosure with respect to certain components but this does not warrant claims of the enormous breadth recited."

See *Ex parte Herzog, Hershberg, and Coan*, 115 USPQ 195 (Bd. Pat. App. & Int. 1956)

affirming the examiner, and stating:

"it becomes obvious that the expressions defining the organic acids used.....are inclusive of inoperative materials and go far beyond the adequately disclosed subject matter of the specification."

See also: *Schering Corporation v. Gilbert et al.*, 68 USPQ 84 (2d Cir. 1946)

It was shown in evidence and by way of admissions elicited by the defendants from the plaintiff before trial that one skilled in the art of organic chemistry may start in the group of the acetic acid radical and the radicals of homologues of acetic acid to which the patent relates, for instance, with the simple hydrocarbon called methane and theoretically progress along the series in the general group called alkanes from one substance to another by increasing the size of the molecules in steps of one carbon atom and two hydrogen atoms. At least formulas for such substances, as well as for others, can be written in an indefinite chain. Also it was shown that for the hydrogen atoms of the alkane molecules the atoms of what are called halogens may be substituted and so may the atoms of other groups including the residue of the hydrocarbon benzene. The latter is represented in chemical formulas by a hexagon which is called the benzene ring and, as changes in the atomic structure of the molecule occur, the ones introduced take varying positions within the ring which positions determine the nature of the compound.

Theoretically a multitude of substances not as yet found in nature and not as yet compounded could be synthesized, if skilled organic chemists were given the time and materials with which to work, and actually the formulas for them could be written. There is, however, a practical limit upon synthesis, though the extent of that is not fully known, for some of the new theoretical compounds might be impossible to create, and some would be so unstable that they would disintegrate either at once or in short periods of varying length. Moreover, while analogy is at times useful, organic chemistry is essentially an experimental science and results are often

uncertain, unpredictable and unexpected.

And Nationwide Chemical Corporation, et al. v. Wright, et al., 192 USPQ 95 (M.D. Fla. 1976)

“with respect to generic claims to chemical and biological inventions, the scope of the claims is limited to what those skilled in the art could reasonably predict from the inventor's disclosure. This precept recognizes that one skilled in these chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances. Thus, in so-called “chemical” patent law practice, the claims of a patent are limited by the scope of what the disclosure reasonably teaches to one skilled in the art.”

In re Prutton, 96 USPQ 147 (C.C.P.A. 1952)

“The complete list of organic compositions includes, in generic form, most of the organic compounds found discussed in ordinary textbooks of organic chemistry..... It appears to be appellant's view that a selection of an unsaturated hydrocarbon from the first list and of a sulphide of phosphorus from the second list will provide support for the claims here under discussion. The Examiner holds, and properly we think, that the presentation of such lists from which reagents may be selected is not a sufficient disclosure to support claims to a particular class of reaction product which might be produced by proper selection of reagents and determining the conditions of reaction.”

In re Walker, 22 USPQ (C.C.P.A. 1934)

“It is true, as argued by counsel, that appellant is entitled to claim not only the substance enumerated by him in his specification, but also their equivalents. However, in cases of this character, involving chemicals and chemical compounds, many of which of course differ radically in their properties, it must appear in the specification, either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that “the chemicals or chemical combinations included therein were generally capable of accomplishing the desired result.” See *In re Ellis*, 37 App. D. C. 203; *In re Dosselman*, 37 App. D. C. 211; *In re Langmuir*, 20 C. C. P. A. (Patents) 733, 62 F. (2d) 93.”

In Re Sus and Schaefer 134 USPQ 1962 301-310 (*affirmed*):

“It is, however, consistent with this public purpose embodied in the pertinent statutory requirement that the *invention claimed* shall be no broader than the *invention set forth* in the written description forming a part of the specification.....thus it seems to us that one killed in this art would not be taught by written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that

only *certain aryl radicals* and certain specifically substituted aryl radicals would be suitable for such purposes.” Emphasis in Original.

See *Ex parte WEIL AND SCHLICHTING*, 158 USPQ 620 (Bd. Pat. App. & Int. 1967)

“We will sustain this rejection of the claims as we are in accord with the examiner’s position. We find no support in the disclosure for such compounds encompassed by these claims wherein R 1, R 2, R 3, and R 5 are all the same and selected from the group, lower alkyl, hydroxy, alkoxy, di(loweralkyl)amino and nitro for example. These claims appear to be in the nature of a paper concept wherein all possible substituents have been included in the composition. There are no examples of such compounds which are included within the vast scope encompassed by these claims, although appellants have a considerable disclosure with respect to certain components but this does not warrant claims of the enormous breadth recited.”

The functional groups as given in the claims includes a plethora of compounds, (with the various definition of R’s) which has these functional moieties.,

Claims employing generic substitutions at the point of novelty, such as applicants’, compounds neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

Also because there are inconsistent and differing uses of the word “heterocycle” in the art. The widely used textbook “Organic Chemistry” by Fessenden says on page 451 that the compounds must be aromatic but that any and all of the atoms in the ring may be selected from the entire periodic table. The widely used “Condensed Chemical Dictionary” also implies that a heterocycle must be aromatic but that only 5 or 6 membered ring compounds with sulfur or nitrogen, not every possible atom are included in the meaning of ‘heterocycle’. The less widely used textbook “Introduction to Organic Chemistry” by Streitwieser on page 1061 defines ‘heterocycles’ as both aromatic and non aromatic. It further implies that the nitrogen, oxygen, and sulfur atoms are commonly meant and that any size ring falls under the rubric of the word.

The Board of Patent Appeals and Interferences held, and the court affirmed *In re Hawkins* 179 USPQ 421 that "It must also be noted that the claim terminology is so broad that it does not even require that the heterocyclic group contain a carbon atom. Heterocyclic ring systems containing phosphorus, boron, silicon, and other elements in addition to nitrogen and oxygen without the inclusion of carbon atoms are well-known and could not be expected to produce compounds having the properties herein claimed."

The rejection still stands.

The rejection of the claims under 35 USC 103 still stands.

First of all the amendment to the claims do not overcome the rejection. The claims still include all the various sugars in their R substituents.

The amendment to claim 15 further limits it to specific tumors. It cannot be seen how this limitation can overcome the rejection.

Applicants arguments are that the US documents do not disclose the compounds of the invention and that the Matt Duan et al, Raquel Delgado et al, Kazuto Okimoto et al teaches including cyclodextrin for making drugs more soluble, however it does not teach using the cyclodextrin for the fredericamycin. This may be correct or else it would be a 102 rejection. The Matt Duan et al, Raquel Delgado et al, Kazuto Okimoto et al teaches using cyclodextrin to make drugs more bioavailable. The US patent teaches the frederimycin and way of making them more soluble using polyethylene glycols, sugars etc. Thus the motivation comes from making the compound more bioavailable and thus more effective.

Conclusion

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

R.D.
January 2, 2009